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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/265,585      | 03/10/1999  | PHILIP N. BENFEY     | 5914-066            | 4702             |

7590 06/05/2002  
PENNIE & EDMONDS LLP  
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NEW YORK, NY 10036-2711

EXAMINER

BAUM, STUART F

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1638

DATE MAILED: 06/05/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/265,585

Applicant(s)

BENFEY ET AL.

Examiner

Stuart Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 29-46 is/are pending in the application.
- 4a) Of the above claim(s) 42, 43 and 46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-41, 44 and 45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

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The amendment C filed 9/13/02 has been entered.

Claims 1-28 have been cancelled.

Claims 29-46 have been added. It is noted that the Applicant appears to have mistakenly written " replaced by new claims 29-62" (page 8, last paragraph of present amendment). The Examiner has interpreted the above citation to actually read "claims 29-46". For purposes of compact prosecution, Examiner has proceeded with prosecution of claims 29-46.

During a telephone conversation with Geraldine Baldwin from Pennie & Edmonds LLP and Andrew Gonsalves from Nixon Peabody LLP on May 8, 2002, a provisional election was made with traverse to prosecute the invention of Benfey et al Group I claims 29-41 and 44-45 including SEQ ID NO:95 and 96. Affirmation of this election must be made by applicant in replying to this Office action. Claims 42, 43 and 46 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Objection is made to claims 36 and 38 for reading on non-elected material, i.e., "or underexpress". Applicant is advised to amend the claims.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 29-41, and 44-45 are drawn to an isolated nucleic acid of SEQ ID NO:95 encoding a polypeptide of SEQ ID NO:96, transgenic plant, and method of expressing a transgene, classified in class 800 subclass 290 for example.

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- II. Claims 36, 38-39, 42, and 46 are drawn to a plant whose SCARECROW protein is underexpressed, classified in class 800 subclass 290, for example.
- III. Claim 43 is drawn to a transgenic plant expressing a transgene that encodes a ribozyme, classified in class 800 subclass 290 for example.

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the nucleic acid sequences and corresponding method of expressing a transgene can be used to make a different product other than the one stated in Group II, in which the product from the method in Group I is a transgenic plant over-expressing the SCARECROW protein. In addition, the product of Group II can be made by any number of processes comprising, antisense, homologous recombination and RNA interference technologies.

Inventions II and III are distinct from each other in starting material, method steps and end products.

Inventions I and III are distinct from each other in starting material, method steps and end products.

Each of Inventions I-III are capable of being separately made, independently used, and the patentability of one does not render the others obvious or unpatentable.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, fields of search, and classification, restriction for examination purposes as indicated is proper.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29-41, and 44-45 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

The claims are drawn to an isolated nucleic acid molecule of SEQ ID NO:95 encoding a polypeptide of SEQ ID NO:96, a vector comprising said nucleic acid molecule and a genetically-engineered plant overexpressing a SCARECROW protein encoded by the nucleic acid molecule of SEQ ID NO:95 wherein cell division in the plant is modified and root and/or stem development is altered, and cell division in the plant roots is increased, and the gravitropism of the stem or hypocotyl is altered wherein the plant is less susceptible to lodging.

The Applicants isolated the *SCARECROW* (*SCR*) gene from *Arabidopsis* and maize and analyzed its expression pattern. They also characterized the *Arabidopsis scr* mutant disclosing that the mutants have less cell division in the root meristem and hypocotyl compared to wild-

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type plants. Applicants purport that over-expressing SCR will increase cell division in the root and stem with a concomitant alteration of the hypocotyl gravitropic response.

Applicants have not presented data supporting their claims of increased cell division in the root and hypocotyl with a concomitant alteration of the hypocotyl gravitropic response when SCR is over-expressed in plants. The only over-expression studies provided is complementing the mutant which is not a readily apparent utility, since one skilled in the art would not use the gene for complementing a mutant to get a wild-type plant, since the wild-type plant is already available.

Claims 29-41, and 44-45 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 36-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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Claims 36-39 are drawn to a genetically-engineered plant overexpressing a SCARECROW protein encoded by the nucleic acid molecule of SEQ ID NO:95 wherein cell division in the plant is modified and root and/or stem development is altered, and cell division in the plant roots is increased, and the gravitropism of the stem or hypocotyl is altered wherein the plant is less susceptible to lodging.

The Applicants isolated the *SCARECROW* (*SCR*) gene from *Arabidopsis* and maize and analyzed its expression pattern. They also characterized the *Arabidopsis scr* mutant disclosing that the mutants have less cell division in the root meristem and hypocotyl compared to wild-type plants. Applicants purport that over-expressing SCR will increase cell division in the root and stem with a concomitant alteration of the hypocotyl gravitropic response. Applicants have not presented data supporting their claims of increased cell division in the root and hypocotyl with a concomitant alteration of the hypocotyl gravitropic response when SCR is over-expressed in plants.

Due to the unpredictable nature of plant transformation, one of skill in the art can not reasonably generate transformed plants with a desired phenotype using a specific isolated gene. Levels of transgene expression in plants are generally unpredictable and vary between independent transformants; this variability is usually explained by differences in transgene copy number and/or integration site (Finnegan and McElroy, 1994. Bio/technology 12: 883-888 pg. 883 2<sup>nd</sup> paragraph) Eshed et al (2001, Current Biology 11:1251-1260 pg 1255 2<sup>nd</sup> paragraph) documented the phenotypes of plants transformed with the 35S CaMV promoter fused to the *KANADII* gene, which is a gene normally expressed in tissues located on the bottom side of young developing leaves. Of the 30 plants that were transformed with the *KANADII* gene, 23

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plants developed only small narrow cotyledons and an arrested meristem, three produced a few radialized leaves and four appeared normal. These results suggest that transforming plants with an endogenously expressed gene in regions of the plant in which it is not normally expressed produces highly unexpected and unpredictable results. For one skilled in the art, undue experimentation would be necessary to produce a plant with a desired phenotype while using an undefined enhancer region as a promoter.

Given the unpredictability of producing a plant with a specific modified phenotype, particularly by transforming a plant with an endogenous gene as stated above; given the lack of working examples of producing a plant with modified or increased cell divisions in the root and/or stem which also exhibit an altered root and/or stem development and hypocotyls that have an altered gravitropic response, given the lack of guidance in the specification for producing and identifying the claimed phenotypes, it would require undue experimentation by one skilled in the art to practice the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36, 38, and 39 and all subsequent dependent claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 36 is indefinite and vague in the recitation "modified". Applicant is requested to explicitly state how the cell division in the plant is changed, e.g. increased or decreased.



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Claim 36 is indefinite and vague in the recitation “altered”. Applicant is requested to explicitly state how the root and/or stem development is changed, e.g. thicker stems, or thinner roots.

Claim 38 is indefinite and vague in the recitation “altered”. Applicant is requested to explicitly state how the gravitropism of the stem or hypocotyl is changed.

Claim 39 is indefinite and unclear in the recitation “less susceptible”. This is a relative statement and the Applicants do not explicitly state the metes and bounds of the range of acceptable lodging compared to a plant exhibiting unacceptable lodging. Applicant is requested to state the parameters by which an individual can measure and quantify the respective lodging phenotypes.

Claims 29-41, and 44-45 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide of SEQ ID NO:95 encoding a polypeptide of SEQ ID NO:96.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart Baum whose telephone number is (703) 305-6997. The examiner can normally be reached on Monday-Friday 8:30AM – 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 or (703) 305-3014 for regular communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the legal analyst, Kim Davis, whose telephone number is (703) 305-3015.

Stuart Baum Ph.D.

May 29, 2002

**ELIZABETH F. McELWAIN**  
**PRIMARY EXAMINER**  
**GROUP 1600**

